35. A method of producing antibodies to an antigen of human immunodeficiency virus type 1 (HIV-1), said method comprising:

(a) providing an antigen of HIV-1, wherein said antigen is encoded by a nucleic acid fragment extending from the restriction site *Kpn*I at about coordinate 3500 to the restriction site *Bgl*II at about coordinate 6500 of plasmid λ-J19; and

(b) raising antibodies against said antigen.

36. A method of producing antibodies to an antigen of human immunodeficiency virus type 1 (HIV-1), said method comprising:

(a) providing an antigen of HIV-1, wherein said antigen is encoded by a nucleic acid fragment extending from the restriction site *Pst*I at about coordinate 800 to the restriction site *Kpn*I at about coordinate 3500 of plasmid λ-J19; and

(b) raising antibodies against said antigen.--

REMARKS

Reconsideration of this application is respectfully requested.

Upon amendment, claims 26-31 and 34-36 are pending in this application, with claims 26-31 withdrawn from consideration. Applicants have canceled claims 23, 32, and 33. Claims 34, 35, and 36 are new, and correspond to claims 23, 32, and 33, respectively. In submitting new claims 34-36, applicants have amended claims 23, 32, and 33 to italicize the restriction enzyme names, and have deleted part (c). As detailed

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below, new claims 34-36 are fully supported by the specification. No new matter enters by amendment.

Claims 23, 32, and 33 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants traverse the rejection.

The Examiner states that the rejection is not based on enablement concerns. Paper No. 34 at 3. The Examiner does not dispute the scientific findings that the skilled artisan, at the time of filing, provided with a restriction fragment capable of encoding a known antigen, could express and purify the antigen of interest and employ this antigen to generate antigen-specific antibodies. Id. Rather, the Examiner alleges that the specification fails to convey to the skilled artisan that applicants were in possession of the claimed invention.

Specifically, the Examiner alleges that the specification does not teach that the claimed restriction fragments encode the viral antigens of interest because the coding potential of the claimed restriction fragments is not readily manifest from the specification, the disclosure does not provide the nucleotide sequence of any of these restriction fragments, and the specification does not provide any evidence that *bona*

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fide viral antigens were produced from these fragments or that antigen specific antibodies were actually produced.

Applicants respectfully disagree with the basis for this rejection. The Examiner appears to require a working example or nucleotide sequence in order for applicants to be in possession of the claimed invention, and for the specification to fulfill the written description requirement of 35 U.S.C. § 112, first paragraph.

Applicants submit that no nucleotide sequence information is required for possession of the claimed **method**. In light of the fact that the Examiner does not dispute the enablement of the claimed invention **in the absence of sequence information**, applicants respectfully submit that the requirement for a nucleotide sequence, **which is neither required nor recited in the claims**, cannot be maintained.

Furthermore, applicants are unaware of any legal precedent that would require a working example to satisfy 35 U.S.C. § 112. Rather, a specification need not contain a working example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation. In re Borkowski, 433 F.2d 904, 908, 164 U.S.P.Q. 642, 645 (C.C.P.A. 1970). Since the Examiner has apparently conceded that the claimed invention is enabled, applicants submit that the Examiner's requirement for a showing of a working example is inconsistent with the court's decisions that such experimental evidence is not required.

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Furthermore, the Examiner has presented no reasons to doubt that the claimed restriction fragments encode the viral antigens of interest. Rather, as illustrated in Wain-Hobson et al., 1985, the claimed restriction fragments do encode viral antigens of interest.

The Examiner further contends that the disclosure fails to provide a suitable written description of the method steps involving the production of an antigen from the restriction fragments, raising antibodies against the antigen, and recovering antigen-specific antibodies. Applicants traverse the rejection.

The test for sufficiency of support in a application is whether the disclosure reasonably conveys to the artisan that the inventor had possession of the claimed subject matter at the time of filing. Ralston Purina Co. V. Far-Mar-Co., Inc., 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985). Applicants submit that the written description requirement of 35 U.S.C. § 112, first paragraph, has been fulfilled since the specification reasonably conveys that applicants were in possession of the claimed **method of producing antibodies**.

The λ-J19 clone was deposited at C.N.C.M. on September 11, 1984. (Specification at 14.) Therefore, the specification reasonably conveys applicants had possession of the λ-J19 clone of HIV-1 at the time the application was filed.

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The specification teaches a detailed restriction map of the λ-J19 clone. (Id. at Figs. 1 and 2.) On pages 4-5, bridging paragraph, the specification teaches specific restriction fragments of the λ-J19 clone:

> The invention further relates to other preferred DNA fragments corresponding substantially to those which in relation to the abovesaid restriction map extend respectively:
> -from approximately KpnI (6100) to approximately BglII (9150) . . . from approximately KpnI (3500) to approximately BglII (6500). . . from approximately Pst (800) to approximately KpnI (3500). . . .

Therefore, the specification teaches DNA fragments extending from approximately *Kpn*I (6100) to approximately *Bgl*II (9150), from approximately *Kpn*I (3500) to approximately *Bgl*II (6500), and from approximately *Pst* (800) to approximately *Kpn*I (3500). The specification further teaches that these restriction fragments correspond, at least in part, to the *env*, *pol*, and *gag* genes, respectively. (Specification at 4-5, bridging paragraph.) Therefore, the specification reasonably conveys that applicants had possession of the claimed restriction fragments of the λ-J19 clone of HIV-1 at the time the application was filed.

On pages 13 and 14, the specification teaches detailed methods of expressing HIV-1 antigens encoded by restriction fragments of the λ-J19 clone. For example, on page 13, lines 13-19, the specification teaches:

> The DNA according to the invention can be used also for diagnostic purposes as well as for the production of LAV viral antigens for diagnostic purposes as well as for the production of a vaccine against LAV. Of particular advantage in that respect are the DNA fragments coding core (gag

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region) and for envelope proteins, particularly the DNA fragments extending from *Kpn*I (6100) to *Bgl*II (9150).

Applicants further point out that the specification teaches that an antigen of the invention "[c]an be identified by simply screening the recombinants with antibodies against LAV antigens." (Specification at 13, lines 31-33.) Therefore, the specification reasonably conveys that applicants had possession of methods to produce antigens from restriction fragments of the λ-J19 clone of HIV-1 at the time the application was filed.

The specification teaches, referring to the restriction fragments of the invention, that "All of the above (a-d) can be **used in diagnostics as sources of immunogens** or antigens . . . ." (Specification at 14, paragraph 1; emphasis added.) Immunogens are substances that, when administered to a host animal, produce an immune response involving the production of antibodies and the activation of T cells. Brock and Madigan at 427 (Exhibit 1). Antigens are substances that react with either antibodies or activated T cells. Id. Most antigens are also immunogens. Id.

Applicants submit that, since the specification teaches the **use of an HIV-1 antigen as an immunogen**, the specification conveys to the skilled artisan the use of HIV-1 antigens for raising antibodies against HIV-1 antigens. As described above, immunogens are substances that, when administered to a host animal, produce an immune response involving the production of antibodies.

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When the skilled artisan read the passages in the specification describing the use of λ-J19 restriction fragments to produce **antigens, which bind anti-HIV antibodies, as sources of immunogens**, the skilled artisan would have recognized that the described **use of HIV-1 antigens as immunogens** inherently disclosed methods for raising antibodies against HIV-1 antigens, since use of the term "immunogen" carries with it the implication that the antigen that, when administered to a host animal, will produce an immune response involving the production of antibodies. Applicants submit that the Examiner must consider all that is conveyed to the skilled artisan by the description in the specification of using HIV-1 antigens as immunogens. See In re Wright, 866 F.2d 422, 424, 9 U.S.P.Q. 2d 1649, 1651 (Fed. Cir. 1989).

Likewise, the skilled artisan would also recognize that the antibodies, having been generated by the immunogen, could be recovered. However, solely to expedite prosecution of this application, applicants have removed the recitation of a recovery step from the amended claims.

An applicant need not teach and preferably omits descriptions of well-known techniques from a patent specification. Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1534, 3 U.S.P.Q. 2d 1737, 1743 (Fed. Cir. 1987). Therefore, applicants need not include descriptions of well known methods of using immunogens to raise antibodies in the specification.

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Applicants also stress that the specification need not recite the claimed invention literally. In re Wertheim, 541 F.2d 257, 265, 191 U.S.P.Q. 90, 98 (C.C.P.A. 1976). Applicants further note that the burden of showing that the claimed invention is not described in the specification rests on the Office in the first instance, and it is up to the Office to give reasons why a description not in *ipsis verbis* is insufficient. Id.

Applicants submit that the teachings of the specification would have conveyed to the skilled artisan that applicants had possession of the claimed method of producing antibodies at the time the application was filed. Accordingly, applicants respectfully submit that the requirements under 35 U.S.C. § 112, first paragraph, have been fulfilled, and request withdrawal of the rejection.

For the foregoing reasons, applicants believe that this application is now in condition for allowance. In the event the Examiner disagrees, he is invited to call the undersigned to discuss the remaining issues.

If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 06-0916. If a fee is required for an

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extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested, and the fee should also be charged to our Deposit Account.

Respectfully submitted,

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By: _____
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Dated: December 2, 1998

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